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FILED

SEP 14 2000

AT 8:30.....  
WILLIAM T. WALSH M  
CLERK

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

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BIO-TECHNOLOGY GENERAL CORP.

Plaintiff,

v.

DURAMED PHARMACEUTICALS, INC.

Defendant.

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Civil Action No. 00-cv-4509 (NHP)

**COMPLAINT**

Plaintiff Bio-Technology General Corp. ("BTG"), for its Complaint against Duramed Pharmaceuticals, Inc. ("Duramed"), alleges as follows:

**THE PARTIES**

1. BTG is a corporation organized under the laws of the State of New Jersey, having its headquarters and principal place of business at 70 Wood Avenue South, Iselin, New Jersey 08830. Duramed is a corporation organized under the laws of the State of Delaware, having a

principal place of business at 6040 Duramed Drive, Cincinnati, Ohio 46213.

**NATURE OF ACTION**

2. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* and the Federal Declaratory Judgement Act, 28 U.S.C. §§ 2201 and 2202.

**JURISDICTION AND VENUE**

3. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

4. This Court has personal jurisdiction over Duramed in that Duramed is registered to do business, and regularly conducts business, in this District.

5. Venue is proper in this District pursuant to 28 U.S.C. §§1391(c) and 1400(b).

**THE PATENT IN SUIT**

6. U.S. Patent Re. 35,724 (the "Pasquale reissue patent") was legally and duly issued on February 3, 1998 as a reissue of U.S. Patent 4,921,843 (the "Pasquale original patent"). A copy of the Pasquale reissue patent is attached as Exhibit A. A copy of the Pasquale original patent is attached as Exhibit B.

7. BTG has been and continues to be the owner of the Pasquale reissue patent.

8. The Pasquale reissue patent covers Mircette® Tablets which are marketed under license by Organon Inc. ("Organon").

**COUNT ONE: INFRINGEMENT PURSUANT TO 35 U.S.C. § 271(e)(2)(A)**

9. Duramed has filed in the U.S. Food and Drug Administration an Abbreviated New Drug Application ("ANDA"), No. 75-863, for a generic version of Mircette® Tablets that contained a certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic

Act (*i.e.*, a "Paragraph IV certification") with respect to the Pasquale original patent.

10. On August 1, 2000, Duramed sent a notice of Paragraph IV certification to Organon stating, *inter alia*, that Duramed "seeks to obtain approval to engage in the commercial manufacture and sale of its version of Mircette™ Tablets prior to the expiration date of October 20, 2008" which is the date of expiration of the Pasquale reissue patent. Organon received Duramed's notice of Paragraph IV certification on or about August 8, 2000.

11. The Pasquale reissue patent, which covers Mircette® Tablets, also covers Duramed's generic version of Mircette® Tablets.

12. Because Duramed "seeks to obtain approval to engage in the commercial manufacture and sale of its version of Mircette™ Tablets prior to the expiration date of October 20, 2008", Duramed has infringed the Pasquale reissue patent pursuant to 35 U.S.C. § 271(e)(2)(A).

**COUNT TWO: DECLARATORY JUDGMENT OF INFRINGEMENT**

13. Paragraphs 1 through 12 are incorporated herein by reference.

14. Upon information and belief, Duramed is systematically attempting to meet the applicable regulatory requirements to market its generic version of Mircette® Tablets before the expiration of the Pasquale reissue patent.

15. Duramed's generic version of Mircette® Tablets will infringe the Pasquale reissue patent.

16. Duramed's actions, accordingly, have created a substantial controversy between BTG and Duramed of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of infringement.

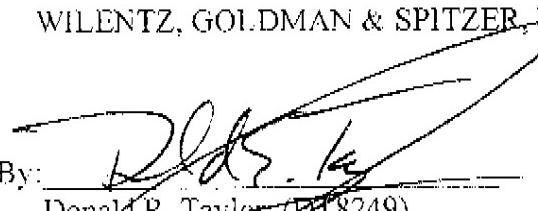
**PRAYER FOR RELIEF**

WHEREFORE, BTG respectfully prays that this Court:

- a. Enter judgment that Duramed has infringed the Pasquale reissue patent;
- b. Enter judgment declaring and adjudging that Duramed will infringe the Pasquale reissue patent by its threatened acts to manufacture and sell a generic version of Mircette® Tablets prior to the expiration date of the Pasquale reissue patent;
- c. Issue an order that the effective date of any approval of ANDA No. 75-863 shall not be earlier than the expiration date of the Pasquale reissue patent;
- d. Issue preliminary and permanent injunctions enjoining Duramed, its officers, agents, servants and employees, and those persons in active concert or participation with any of them from commercially making, using, offering for sale or selling its generic version of Mircette® Tablets which is the subject of ANDA No. 75-863, and any other generic version of Mircette® Tablets, prior to the expiration of the Pasquale reissue patent;
- e. Award BTG its attorney fees and costs pursuant to 35 U.S.C. §§ 271(e)(4) and 285; and
- f. Award BTG such other and further relief as this Court deems just and proper.

WILENTZ, GOLDMAN & SPITZER, P.C.

Dated: September 14, 2000

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